RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAUL P. LATTA

Appeal 2007-1152
Application 10/660,924
Technology Center 1600

Oral Hearing Held: Wednesday, September 12, 2007

Before ERIC GRIMES, LORA M. GREEN, and RICHARD M. LEBOVITZ, Administrative Patent Judges

ON BEHALF OF THE APPELLANTS:

DANIEL E. ALTMAN, ESQ.
Knobbe, Martens, Olson & Bear, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
(949) 760-0404

The above-entitled matter came on for hearing on Wednesday, September 12, 2007, commencing at 2:12 p.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, 9th Floor, Hearing Room A, Alexandria, Virginia, before Jan M. Jablonsky, Notary Public.

JUDGE GRIMES: Good afternoon, Mr. Altman.

MR. ALTMAN: Good afternoon.

JUDGE GRIMES: As you probably know, you'll have 20 minutes to address each of the separate applications that we're going to talk about today.

I guess we'd like to start with Serial Number 10/660924. And then once we're done talking about that one, we can move on to the other one.

JUDGE LEBOVITZ: Mr. Altman, with respect to that one, could you begin off with the new matter rejection? Because the enablement was pretty well addressed. So can we just start off with the new matter description rejection?

MR. ALTMAN: Okay. I just wanted to say a couple of background information, a little bit of background information related to both cases, if that's okay.

JUDGE LEBOVITZ: Sure, thanks.

MR. ALTMAN: Both of these cases relate from the same discovery and my client wanted me to present to you that he is an independent inventor, that he's worked in the laboratories of several different prominent researchers both at universities and companies. And so he's been working very diligently on this for quite some time as you can see from the

record. So that was just some background that my client specifically asked me to provide to you.

And you asked me to address the new matter issue. It's fairly clear what the support in the specification for this particular limitation that the Examiner objected to.

JUDGE LEBOVITZ: Can, I? I'm sorry, just to rephrase it, the Examiner at the very end, because there were a number of issues in there, at the very end of his rejection he points out that no where do you teach the one-step of administering a preventive dose.

MR. ALTMAN: I see. Okay. So, because the particular issue is the issue of where do we get the one to two orders of magnitude less and that's not the issue that you're interest in?

JUDGE LEBOVITZ: Well, I think that's coupled to that and I think that if you look at the end of the answer, the Examiner clearly stated in the spec, in particular, I think he alleged in the summary of the invention the two-step where you administer a tolerizing dose followed by a curative dose. So if you could just point out the support for the single dose?

MR. ALTMAN: I understand. Okay. Let me find this section again. Okay. On page 19 of the specification is the section which is on implants for prevention of diseases. And the section that is relevant has to do with diabetes. And this section relates to the implants of islets which are conducted for the prevention of diabetes. And the section relates to the identification of patients for preventions of disease and it says that what happens is that the individuals are determined to be at risk of developing diabetes and then the amount of dose which is used for tolerizing is the same for the tolerizing dose in the curative area.

And the whole point of this aspect of the invention is to prevent diabetes from developing. If Diabetes is prevented from developing there would be no point to introducing a curative dose. So the entire purpose of this section of the invention is that there is no diabetes to treat. And the second step has to do with the curative, has to do with the curative aspect of this invention.

JUDGE LEBOVITZ: But if you read the whole specification, the concept comes across that what we're going to do is to tolerize a patient to an allograft and then we're going to introduce a curative dose of the allograft so we can grow a pancreas. And in that sense, will prevent the onset of diabetes by having the transplanted pancreas present as the old pancreas, I guess, is dying or is being destroyed through whatever mechanisms. But right here, since it does refer to a tolerizing implant, to me that implies or says that you are tolerizing to the curative dose.

MR. ALTMAN: I see. The idea behind this aspect of the invention is that it's well-known that diabetes is an autoimmune disease and that the idea behind tolerizing in this aspect of the invention, which should be clear to one having ordinary skill in the art who has read all of the literature explaining that diabetes type 1 is an auto-immune disease, the idea here is to prevent that autoimmune reaction from occurring in the first place.

And so, if that autoimmune reaction does not occur, it's clear that there would be no reason to introduce the second curative dose.

JUDGE LEBOVITZ: Well, I see the prevention of the auto-immune response to have been stated in Dr. Sharp's declaration. But is that in the specification as well?

MR. ALTMAN: Well, what it says is that the physician determines sat what point in the course of the disease it would be most advantageous to intervene. And it's that part of the specification that would lead one having ordinary skill in the art to understand that the purpose of this is to intervene in the autoimmune process. It certainly was the intent of the inventor to intervene in the prevention of diabetes by preventing the ideology of the disease from carrying out its full course.

JUDGE GRIMES: Is there any discussion in the specification of this tolerizing implant having an effect in adducing tolerization of the patient's own cells? My impression is you're tolerizing with respect to what you want to implant later on.

MR. ALTMAN: That is the subject matter of the other case that's at issue today.

JUDGE GRIMES: Right, but does the spec actually talk somewhere about the tolerizing implant effecting the body's immune reaction against its own cells?

MR. ALTMAN: Well, there is a connection with myasthenia gravis. There is Example 5, and also Example 7, which are prevention of hemophilia and prevention of myasthenia gravis. These are of course extensions of the invention which are not claimed, but these relate to these autoimmune disorders that can be prevented using the topic of the present invention.

So Example 7 specifically identifies myasthenia gravis as an autoimmune disorder. And in Example 7, what is happening is there's a single administration of the encapsulated cells and that results in tolerization to the autoimmune reaction, which would typically occur in myasthenia

gravis. Example 6 would be similar too. It's just relating to a transplant. That's also somewhat, a little bit different, but somewhat of an autoimmune reaction. So in combination with these examples--

JUDGE GRIMES: Could I? Oh, I see. Never mind. I was just getting confused what were examples. Go on, sorry.

MR. ALTMAN: So, these examples show that a one-step process was intended for an autoimmune disorder, such as diabetes melitis.

JUDGE LEBOVITZ: Well, it looks like Example 7 seems to be the closest. Right, where there's just one tolerizing dose given that prevents a disorder. I think in the others to me, at least in Example 6, they're tolerizing and then giving a complete organ again.

MR. ALTMAN: Example 6, you're right about that.

JUDGE LEBOVITZ: Yeah.

MR. ALTMAN: Yeah, Example 7 is clearly only one dose of the myasthenia gravis and it's the same principle that would be used in treatment of diabetes.

JUDGE LEBOVITZ: Was that addressed? I don't think that was addressed in the Declaration. I'm just asking the question.

MR. ALTMAN: I'm not sure I understand what.

JUDGE LEBOVITZ: I was just asking if you remembered whether Dr. Sharp had brought that Example up in his deck?

MR. ALTMAN: No. I don't believe he did discuss it specifically.

So the entire idea behind this aspect of the invention was always to give a single step, and that's what's disclosed in Example 7. And

diabetes, although there's not an example of it, is specifically exemplified in the paragraph on page 19, line 9.

Shall I address briefly the other issue? You said it's fairly well addressed in writing.

JUDGE LEBOVITZ: I don't really think you need to, but of course if you want to or if you want to summarize it, feel free to do that.

MR. ALTMAN: Okay. I'll just do it very briefly then.

The issue here that the Examiner raised is whether it was predictable that the invention could be used in mammals other than mice. And we seem to have gotten into a match of dueling papers with the Examiner. And I wanted to point out that the MPEP sets forth a standard for what type of data can be used in connection with whether the invention can be viewed as predictable.

And the standard that the MPEP sets forth is it's much more in line with the standard that we have been proposing then, what the Examiner has been proposing. And the data that was presented in Dr. Sharp's initial Declaration, it was really, truly outstanding. It was incredible that these mice that ordinarily develop diabetes as an autoimmune response, without any treatment dose were able to remain diabetes free for as long as nine months, which was the term of that study. So it was somewhat surprising to the inventor of course that the Examiner found it unpersuasive.

And I wanted to point out also that at least one of the groups, 100% of the mice remained diabetic free between the course of the experiment.

So, if there are any other questions I can answer about that aspect, I'd be happy to. Or about the Declaration, you asked earlier.

JUDGE LEBOVITZ: No. That was fine.

MR. ALTMAN: Okay.

JUDGE GRIMES: Any other questions?

JUDGE LEBOVITZ: No.

JUDGE GRIMES: That's all we need to discuss about this particular case. Thank you, very much.

[Whereupon, at 2:26 p.m., the hearing was concluded.]